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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/806,253
First Named Inventor	:	David C. BAULCOMBE
Filed	:	March 22, 2004
TC/A.U.	:	1638
Examiner	:	N/A
Docket No.	:	101044.53943D1
Title	:	Gene Silencing



**PETITION TO MAKE SPECIAL PURSUANT TO § 1.102(D) AND  
REQUIRED STATEMENT BY THE UNDERSIGNED PATENT  
ATTORNEY/AGENT**

**Mail Stop =====**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition the Commissioner to make this application special under 37 C.F.R. § 1.102(d) according to the guidelines of MPEP § 708.02 (II) which specifies that applications may be made special because of actual infringement. As required by 37 C.F.R. § 1.102(d), the fee under 37 C.F.R. § 1.17(h) is also enclosed.

**A. The Method Claims of US Patent Application 10/806,253 Are  
Infringed by the SiRNA Detection Kit Marketed by Ambion,  
Inc., The MiRacULS miRNA isolation and labeling kit by  
Kreatech and Various Researchers in the Field**

The subject application relates to biotechnology. Particularly, this application relates to a method of detecting the occurrence of post-transcriptional gene silencing (PTGS) in an organism by detecting the presence of short RNA molecules (SRMs) having a size of 25 nucleotides, plus or minus 1, 2, 3, 4

or 5 nucleotides. A parent to the present application, USSN. 09/491,549, has now issued to patent as US 6,753,139. That patent claims methods of detection of PTGS in plants by detecting the presence of SRMs as above defined, and that patent has been licensed to a number of major agricultural biotechnology licensees. The present application extends the methods already granted in the 6,753,139 patent to organisms other than plants. It is well known in the literature that PTGS occurs in a wide range of organisms, from plants, to nematodes, to drosophila, to mammals, and in every case, as disclosed and claimed in the present application, such PTGS is associated with the presence of SRMs as above defined in cells undergoing silencing.

**B. This Patent Application is a Major Asset of The Subject Assignee**

Applicants respectfully attest to the fact that this patent application is a major asset of the subject assignee, PBL. This is further supported by the Statement of Gerard Bencen.

**C. That The Development of This Technology Will be Significantly Impaired if Examination is Delayed**

Applicants respectfully submit that the development of the technology covered by this patent application will be significantly impaired if prosecution is not expedited. Applicant's belief is supported by their knowledge that a number of different entities, including, for example, Ambion, which sells kits for detection of SRMs, and Kreatech which sells similiar small RNA isolation and labeling kits whether for use in plant cells or in organisms generally, are apparently

infringing the technology covered by this patent application.

Claim 32 of the present application reads as follows:

A method of detecting the silencing of a target gene in an organism, wherein said silencing is initiated by introduction of an exogenous nucleic acid, which method comprises the steps of

- i) obtaining a sample of material from said organism;
- ii) producing a nucleic acid from said sample,
- iii) analyzing said extract such as to determine the presence or absence of short RNA molecules which are 21-25 nucleotides in length (SRMs) in said extract,
- iv) characterizing any SRMs which are present in said extract such as to determine sequence identity or similarity with said target gene, and
- v) correlating the presence of said SRMs having sequence identity or similarity with said target gene in the extract with the occurrence of gene silencing in said organism.

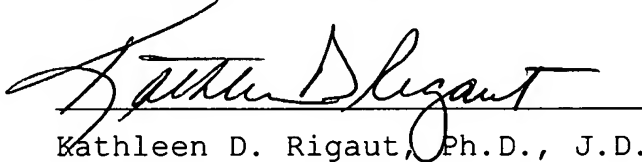
Attached hereto as Exhibit A are Tech notes and a product description of a method and kit for detecting small RNA molecules (e.g., siRNA or miRNA) marketed by Ambion. Clearly, this method and kit infringes pending claim 32. Also see a press release from Kreatech attached hereto as Exhibit B, which describes the development of the miRNAacULS kit for detection of miRNA and siRNA.

Additionally, researchers and pharmaceutical companies developing PTGS based therapies detect the presence of SRMs in the course of their development of promising new therapies. See, for example, Exhibit C, Anderson and Akkina, 2005, where the production of short interfering RNA molecules is confirmed

in Figure 5 in Magi-X4 cells and Ghost-R5 cells, in experiments aimed at defining a PTGS-based anti-HIV treatment. PBL believes that the use of the Ambion kits and detection of SRMs as evidenced in the work of Anderson and Akkina 2005, for example, infringe the claims being pursued in this application. Also see Exhibit D, a research paper entitled "A Simple and Rapid method to detect plant siRNAs using Nonradioactive Probes by Goto et al. which appeared in Plant Molecular Biology Report 21:51-58 (2003). The method disclosed entails isolating nucleic acid from plants where silencing is occurring and characterizing the sequences of the isolated short RNA molecules using sequence specific probes. Finally, Exhibit E, by Kawasaki et al., also describe methods for the detection of siRNA in mammalian cells which clearly infringes claim 32 above.

Based on the foregoing, Applicants respectfully request that this Petition to Make Special should be granted. However, if any issues remain outstanding, the Patent Office is respectfully requested to contact the undersigned so that prosecution may be expedited.

Respectfully submitted

A handwritten signature in cursive script, appearing to read "Kathleen D. Rigaut", written over a horizontal line.

Kathleen D. Rigaut, Ph.D., J.D.

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Enclosures: Exhibits A-E

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PETITION FEE**  
Under 37 CFR 1.17(f), (g) & (h)  
**TRANSMITTAL**  
(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/806,253
Filing Date	March 22, 2004
First Named Inventor	David C. Baulcombe, et al.
Art Unit	1638
Examiner Name	Ashwin D. Mehta
Attorney Docket Number	4476-P02094US01

Enclosed is a petition filed under 37 CFR 1.102(d) that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of \$ 130.00 is enclosed.

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. For transmittal of processing fees under 37 CFR 1.17(f), see form PTO/SB/17i.

**Payment of Fees** (small entity amounts are NOT available for the petition fees)

☒ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 04-1406:

☐ petition fee under 37 CFR 1.17(f), (g) or (h) ☒ any deficiency of fees and credit of any overpayments

Enclose a duplicative copy of this form for fee processing.

☒ Check in the amount of \$ 130.00 is enclosed.

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

**Petition Fees under 37 CFR 1.17(f): Fee \$400 Fee Code 1462**

For petitions filed under:

- § 1.36(a) - for revocation of a power of attorney by fewer than all applicants
- § 1.53(e) - to accord a filing date.
- § 1.57(a) - to accord a filing date.
- § 1.182 - for decision on a question not specifically provided for.
- § 1.183 - to suspend the rules.
- § 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
- § 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.

**Petition Fees under 37 CFR 1.17(g): Fee \$200 Fee Code 1463**

For petitions filed under:

- § 1.12 - for access to an assignment record.
- § 1.14 - for access to an application.
- § 1.47 - for filing by other than all the inventors or a person not the inventor.
- § 1.59 - for expungement of information.
- § 1.103(a) - to suspend action in an application.
- § 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.
- § 1.295 - for review of refusal to publish a statutory invention registration.
- § 1.296 - to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
- § 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
- § 1.550(c) - for patent owner requests for extension of time in *ex parte* reexamination proceedings.
- § 1.956 - for patent owner requests for extension of time in *inter partes* reexamination proceedings.
- § 5.12 - for expedited handling of a foreign filing license.
- § 5.15 - for changing the scope of a license.
- § 5.25 - for retroactive license.

**Petition Fees under 37 CFR 1.17(h): Fee \$130 Fee Code 1464**

For petitions filed under:

- § 1.19(g) - to request documents in a form other than that provided in this part.
- § 1.84 - for accepting color drawings or photographs.
- § 1.91 - for entry of a model or exhibit.
- § 1.102(d) - to make an application special.
- § 1.138(c) - to expressly abandon an application to avoid publication.
- § 1.313 - to withdraw an application from issue.
- § 1.314 - to defer issuance of a patent.

  
Signature

Kathleen D. Rigaut, Ph.D., J.D.

Typed or printed name

March 27, 2006

Date

43,047

Registration No., if applicable

This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.